REMARKS

In the Office Action, the Examiner has vacated the previous requirement for restriction, and has set forth a new requirement. Specifically, the Examiner states that this application contains the following groups of inventions which do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. The Examiner requires Applicants to elect a single distinct invention in accordance with 35 U.S.C. §§121 and 372.

Group A Claims 1-10, 12, drawn to a method for detecting a cancer, by detecting the inhibin protein.

Group B Claims 1-10, 12, drawn to a method for detecting predisposition to a cancer, by detecting the inhibin protein.

Group C Claims 1-10, 12, drawn to a method for detecting a cancer, by detecting the inhibin nucleic acid.

Group D Claims 1-10, 12, drawn to a method for detecting predisposition to a cancer, by detecting the inhibin nucleic acid.

Group E Claim 51, drawn to an inhibin nucleic acid.

Group F Claims 51-54, 78, drawn to an antibody to or a modulator of an inhibin protein.

Group G Claims 55-56, 61-62, 67-69, 73, 75, drawn to a method for modulation invasiveness or treating cancer, using a modulator of inhibin protein.

Group H Claims 55-56, 61-62, 67-69, 73, 75, drawn to a method for modulating invasiveness, or treating cancer, using an inhibin nucleic acid, or its modulator.

Group I Claims 61062, drawn to a prophylaxis or treating of predisposition to cancer development, using a modulator of inhibin protein.

Group J Claims 61-62, drawn to a prophylaxis or treating of predisposition to cancer development, using a modulator of inhibin nucleic acid.

Group K Claim 78, drawn to a modulator of inhibin nucleic acid.

In connection with Group A, the Examiner has also stated that a method of detecting each cancer, as recited in claim 10, constitutes a single distinct invention. Similar statements are made in connection with Groups B, C, D, G, H, I and J. In a telephonic communication on September 3, 2008, the Examiner clarified to the undersigned attorney that Applicants must also elect a specific cancer if a group election is made for one of Groups A, B, C, D, G, H, I or J.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Group A, claims 1-10, 12, drawn to a method for detecting a cancer, by detecting the inhibin protein. Applicants further provisionally elect neoplasm of prostate in connection with Group A for continued prosecution. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application in the event that the pending restriction requirement is made final. However, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

A requirement for restriction presupposes an analysis of the subject application in light of the rules governing this practice, i.e., 37 C.F.R. §1.499 and PCT Rules 13.1 and 13.2. PCT Rule 13.1, first sentence, states: "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ('requirement of unity of invention')." (Emphasis added.) PCT Rule 13.2 states: "The expression "technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." (Emphasis added.)

The Examiner alleges that the subject matter listed as Groups A-K do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The Examiner alleges that WO98/47526 teaches a method of modulating cell growth by administering inhibin or an inhibin antagonist or agent that modulates the expression of inhibin. The Examiner contends that the technical feature of the claimed invention is inhibin or its modulator. The Examiner reasons that this feature of the present invention lacks novelty and does not define a contribution over WO98/47526.

In the first instance, Applicants respectfully submit that unity of invention is the issue at hand. The Examiner should not rely on an evaluation of novelty or unobviousness based on certain prior art in order to determine whether the requirement of unity of invention is satisfied under PCT Rule 13.1. Applicants should be given the opportunity to argue on merits during prosecution whether the claims are novel and unobvious over certain prior art. Restriction of the claims at this stage would deny Applicants such an opportunity.

Further, Applicants respectfully submit that the claims of Groups A, B, C and D, or at least the claims of Groups A and B, are linked under a single inventive concept and should be examined together. In this regard, Applicants note that the Examiner has based the Restriction Requirement on the allegation that the technical feature which links the present claims, being inhibin or its modulator, lacks novelty and does not make a contribution over WO98/47526. The Examiner alleges that this prior art document teaches a method of modulating cell growth, by administering inhibin or its antagonist, or an agent that modulates the expression of inhibin, wherein the inhibin may be α-inhibin.

Applicants disagree with the Examiner's determination. Applicants respectfully submit that a principal technical feature of the invention resides in the recognition of the link between an increase in the level of inhibin and the shift of a cancer to an advanced/metastatic cancer. Contrary to the Examiner's characterization, the present invention is not "inihibin", *per se*.

Regarding WO98/47526, this document discloses that the onset of prostate cancer could be diagnosed by virtue of a *decrease* in the level of inhibin in a patient. The present application, however, is directed to the determination that in the context of an *existing* cancer, an *increase* in the level of inhibin is indicative of the shift of that cancer to an advanced/metastatic state. As would be appreciated by those skilled in the art, cells which undergo malignant transformation pass through a sequence of stages. Initially there will likely occur pre-malignant changes to these cells followed by their shift to a malignant state. In the context of the malignant state, some cells may then advance to a metastatic state. The disclosures of WO98/47526 and the present application are consistent with the notion that cancer is a multistep process which involves an initial transition from non-malignant status and, in some cases progression of the malignant status from a localized cancer to a metastatic disease. WO98/47526 discloses that the inhibin molecule is decreased in its level of expression in the early stages of the disease, whereas the present application discloses that in the context of the later transition to metastatic disease, inhibin becomes overexpressed. For example, it has been determined in accordance with the present application that as prostate cancer progresses from a low grade to a more advanced state, there occurs a switch in function and expression of the inhibin molecule such that it becomes oncogenic and causes transition of the cancer into the highest grade state and metastatic disease. The switch to an oncogenic state is associated with

an increase in inhibin levels. It is this *increase* in inhibin levels which provides the basis for the presently claimed subject matter defined by the Examiner as Groups A-D.

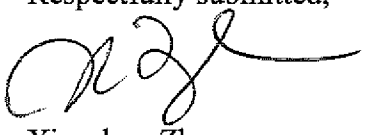
Specifically, Applicants respectfully submit that the claims of Groups A and B are both directed to detecting an increase in inhibin protein, with Group A relating to a determination of the onset of an advanced neoplasm, and Group B relating to a determination of predisposition to the onset of an advanced neoplasm. Similarly, the claims of Groups C and D are both directed to detecting an increase in inhibin nucleic acid, with Group C relating to a determination of the onset of an advanced neoplasm, and Group D relating to a determination of predisposition to the onset of an advanced neoplasm. All of Groups A-D are based on detecting an increase in the inhibin molecule. Therefore, Applicants respectfully submit that Groups A-D are clearly linked to each other under a single inventive concept of detecting an increase in inhibin levels. Because WO'526 discloses absolutely nothing about an increase in inhibin levels in the context of any stage of any cancer, this technical feature of the present invention is a special technical feature and defines a contribution over the prior art. Therefore, the claims of Groups A-D should be examined together.

With respect to the election of neoplasm of prostate, Applicants respectfully submit that the Examiner has not provided any reasoning as to why diagnoses of different cancers would constitute distinct inventions. Rather, Applicants respectfully submit that diagnoses of different cancers are all based on the single inventive concept of detecting an increase in inhibin levels, and therefore methods in respect to different cancers should also be examined together.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined groups, one from another, as presented by the Examiner.

Accordingly, it is respectfully submitted that the present claims satisfy the requirements for unity of invention. Applicants respectfully urge that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims, or at least the claims of Groups A-D, or Groups A-B at the minimum.

Respectfully submitted,



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